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10/026,925	12/18/2001	Robert Charles Ladner	DYAX/004	6828

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EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
Restriction Purposes Only	10/026,925	LADNER, ROBERT CHARLES	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1, 22 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR1 of sequence X-Y-X-M- X, classified in class 435, subclass 320.1 or 5.

Group 2. Claims 1, 22 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR1 of sequence S/T-S/G/X-S-G-X-Y-Y-W, classified in class 435, subclass 320.1 or 5

Group 3. Claims 1, 22 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR1 of sequence V-S-G-G-S-I-S-X-X-X-Y-Y-W-X (SEQ ID NO 1), classified in class 435, subclass 320.1 or 5.

Group 4. Claims 3, 24 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR2 of SEQ ID NO 2, classified in class 435, subclass 5, or 320.1.

Group 5. Claims 3 and 24 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR2 of SEQ ID NO: 3, classified in class 435, subclass 320.1 or 5.

Group 6. Claims 3 and 24 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR2 of SEQ ID NO: 4, classified in class 435, subclass 320.1 or 5.

Group 7. Claims 3 and 24 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR2 of SEQ ID NO: 5, classified in class 435, subclass 5 or 320.1.

Group 8. Claims 5, 26 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR3 of SEQ ID NO: 6, classified in class 435, subclass 5 or 320.1.

Group 9. Claims 5, 26 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR3 of SEQ ID NO: 7, classified in class 435, subclass 5 or 320.1

Group 10. Claims 5, 26 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR3 of SEQ ID NO: 8, classified in class 435, subclass 5 or 320.1.

Group 11. Claim 5, 26 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR3 of SEQ ID NO: 9, classified in class 435, subclass 5 or 320.1.

Group 12. Claim 5, 26 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR3 of SEQ ID NO: 10, classified in class 435, subclass 5 or 320.1.

Group 13. Claims 5, 26 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR3 of SEQ ID NO: 11, classified in class 435, subclass 5 or 320.1.

Group 14. Claims 5, 26 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR3 of SEQ ID NO: 12, classified in class 435, subclass 5 or 320.1.

Group 15. Claims 5, 26 (in-part), drawn to a focused library of vectors, in which the variegated DNA encodes a heavy chain CDR3 of SEQ ID NO: 13, classified in class 435, subclass 5 or 320.1.

Groups 16-23. Claims 6, 27 (in-part), each group is drawn to a different focused library of HC CDR3 sequence (SEQ ID NOs 6-13) wherein proportions of amino acids is defined as in claim 6 or claim 27, classified in class 435, subclass 5, 320.1

Group 24. Claim 9 (in-part), drawn to focused library of kappa light chain CDR1 of SEQ ID NO: 14, classified in class 435, subclass 5 or 320.1.

Group 25. Claim 9 (in-part), drawn to focused library of kappa light chain CDR1 of SEQ ID NO: 15, classified in class 435, subclass 5 or 320.1.

Group 26. Claims 11, 32, drawn to focused library of kappa light chain CDR2 having the sequence of 1AS2R41, classified in class 435, subclass 5 or 320.1.

Group 27. Claims 12, 33 (in-part), drawn to focused library of kappa light chain CDR3 of SEQ ID NO: 16, classified in class 435, subclass 5 or 320.1.

Group 28. Claims 12, 33 (in-part), drawn to focused library of kappa light chain CDR3 of sequence QQ33111P, classified in class 435, subclass 5 or 320.1.

Group 29. Claims 12, 33 (in-part), drawn to focused library of kappa light chain CDR3 of sequence QQ3211PP1T (SEQ ID NO: 17), classified in class 435, subclass 5 or 320.1.

Group 30. Claims 14, 35 (in-part), drawn to focused library of lambda light chain CDR1 of SEQ ID NO: 18, classified in class 435, subclass 5 or 320.1.

Group 31. Claims 14, 35 (in-part), drawn to focused library of lambda light chain CDR1 of sequence G24L444344, classified in class 435, subclass 5 or 320.1.

Group 32. Claims 16, 37, drawn to focused library of lambda light chain CDR2 of sequence 4442RPS, classified in class 435, subclass 5 or 320.1.

Group 33. Claims 17, 38 (in-part), drawn to focused library of lambda light chain CDR3 of sequence 45424S4444V, classified in class 435, subclass 5 or 320.1.

Group 34. Claims 17, 38 (in-part), drawn to focused library of lambda light chain CDR3 of SEQ ID NO: 19, classified in class 435, subclass 320.1 or 5.

Further Restriction

In addition to each Group (groups 1-34) detailed above, the claims further read on following patentably distinct Group 35) through group 51). The claims are drawn to different mixtures combinations of individual libraries. Applicants are required to elect one combination for examination. The selected combination will be searched until one nucleotide sequence in the combination is found to be allowable over prior art. If no individual sequence in the combination is found allowable over prior art, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

Each of the following claims is further divided into multiple groups each representing a different combination.

The elected further Group must result in a single specific combination of sequences. ***For this response to be complete, applicants should provide the sequences of elected combination.***

This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each combination is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Group 35) Claims 1, 22, section (4) is drawn to a mixture of vectors in any combination of sequences in different sections 1), 2) and 3). Applicants is required to select one combination nucleic acid sequences which encode one single amino acid sequence in each section. I.e., if applicants elect mixtures of vectors comprising 1) and 2). Applicants are requested to provide the nucleic acid sequence which encodes one single peptide from 1), and the nucleic acid sequence which encodes one single peptide from 2). If the elected combination of sequences are allowable over the prior art, all combinations containing such sequences would be allowable over prior art.

Group 36) Claims 3 and 24 section (5) is drawn to a mixture of vectors in any combination of sequences in different sections 1), 2), 3) and 4). Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 37) Claims 4 and 25, drawn to a mixture of vectors in combination of 1) and 2) equimolar; 3) and 4) in the ratio of 0.54: 0.43: 0.03. Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 38) Claims 5, and 26 section (9), drawn to a mixture of vectors in any combination of sequences in different sections 1), 2), 3), 4), 5), 6), 7) and 8. Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 39) Claims 6 and 27 are drawn to a mixture of vectors in combination of 1) through 8) in which 0.095 of G, Y; and 0.048 of each A, D, E, F, H, I, K, L, M, N, P, Q, R, S, T, V and W. Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 40) Claims 7 and 28 drawn to a mixture of vectors in combination of 1) through 8) in proportion of 01.: 0.14: 0.25: 0.13: 0.13: 0.11: 0.04: 0.10. Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 41) Claims 8 and 29 drawn to a mixture of vectors in combination of 1) through 8) in proportion of 0.02.: 0.14: 0.25: 0.14: 0.14: 0.12: 0.08: 0.11. Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 42) Claims 9 and claim 30, section (3) and **claim 10, claim 31** are drawn to a mixture of vectors in any combination of sequences in different sections 1), and 2). Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 43) Claims 12, and 33, section (4), are drawn to a mixture of vectors in any combination of sequences in different sections 1), and 2) and 3). Applicant is required to select

one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 44) Claims 13 and 34 drawn to a mixture of vectors in combination of 1), 2) and 3) in the ratio of 0.65: 0.1: 0.25. Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 45) Claims 14 and 35 section (3) is drawn to a mixture of vectors in any combination of sequences in different sections 1), and 2). Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 46) Claims 15 and 36, drawn to a mixture of vectors in combination of 1), and 2) in the ratio of 0.67: 0.33. Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 47) Claims 17 and 38, section (3) and **claims 18, 39** are drawn to a mixture of vectors in any combination of sequences in different sections 1), and 2). Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence in each section.

Group 48) Claims 19, 40, each section 1) through (3) is drawn to a mixture of vectors each encoding a different combination of heavy chain CDR1 with either CDR2 or CDR3 , and in any combination of CDR1, CDR2, and CDR3. Applicant is required to select one combination of nucleic acid sequences which encode one single amino acid sequence for each heavy chain CDR.

Group 49) Claims 20, 41, drawn to a mixture of vectors each encoding a different combination of heavy chain CDR2 and CDR3. Applicant is required to select one combination

of nucleic acid sequences which encode one single amino acid sequence for each heavy chain CDR.

Group 50) Claims 21, 42, each section 1) through (7) is drawn to a mixture or combination of vectors each encoding a different combination of heavy chain CDR1, CDR2 or CDR3 with kappa light chain CDR1, CDR2, CDR3; and lambda light chain CDR2; and lambda light chain CDR3; kappa light chain CDR1; kappa light chain CDR3 , and in any combination of CDR1, CDR2, and CDR3. Applicant is required to select one combination of nucleic acid sequences, which encode one single amino acid sequence for each of heavy chain, and light chain CDR.

Group 51) Claim 2 and claim 23 are drawn to a mixture of populations of DNA sequences of section 1), 2) and 3) of claim 22 and present in ratio of 0.80: 0.17: 0.02. Applicant is required to select one combination of nucleic acid sequences for each section.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups 1 through 51, are all drawn to different focused libraries, which variegated DNA sequences encoding different polypeptides of different amino acid sequences. The DNA sequences which encode the different polypeptides, which are structurally distinct from each other. The Inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Thus, restriction between the groups is proper.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C.

121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. (SEE MPEP 803.04)

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different inventions or groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Therefore, these do not create an undo search burden, and restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: In this application all the claims recite a genus of DNA sequences that encode a genus of polypeptides. If either group 1 through 34 is elected, applicants are further requested to elect a single species of nucleic acid sequence, which encodes an ultimate single polypeptide sequence.

For this response to be complete and for search purposes, applicants should provide the amino acid sequence which is encoded by the elected nucleic acid sequence, wherein the sequence at each position is defined by a single amino acid.

The different nucleic acid sequences encoding a different polypeptide sequences are each structurally, and functionally distinct. Thus, species election between the groups is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

18 March 2005